CME 5 (Radiopharmacy / EDQM)
Monday, October 15, 08:00-09:30

Session Title
Validation of Radioanalytical Methods

Chairs
Ellen Pel (Strasbourg)
Clemens Decristoforo (Innsbruck)

Programme

08:00 - 08:30 Sergio Todde (Monza): General Principles on Validation of (Radio)Analytical Methods

08:30 - 09:00 Nicholas Gillings (Copenhagen): EANM Guidelines – Practical Examples

09:00 - 09:30 Ellen Pel (EDQM, Strasbourg): European Pharmacopoeia Guide for the Elaboration of Monographs for Radiopharmaceutical Preparations – Validation of Radioanalytical Methods

Educational Objectives
Upon completion of this CME session the attendee will be aware of:

1. The importance and the impact of validation of radioanalytical methods in the day-by-day activity of a radiopharmacy, including general principles on radioanalytical techniques
2. Perspectives from the European Pharmacopoeia (Ph. Eur.): an overview of the Ph. Eur. Guide for the elaboration of monographs on radiopharmaceutical preparations, currently under revision to include a section on validation of radioanalytical methods
3. How to validate a radioanalytical method; to this regard, practical examples, with useful hints and tips, will be provided

Summary
Quality control is an important part of the activity of a radiopharmacy, and is aimed to verify that radiopharmaceuticals prepared both for diagnostic and therapeutic purposes are of adequate quality and safe for the administration to the patients. Analytical methods may be described in European Pharmacopoeia monographs dedicated to specific radiopharmaceuticals; these monographs provide detailed information on techniques and conditions for analysis, as well as on the acceptance criteria that have to be considered in order to decide whether a radiopharmaceutical preparation is suitable for patient administration or not.
However, radiopharmaceuticals may be newly developed, or a Ph. Eur. Monograph may not be available or, again, pharmacopoeial methods may be changed by the users. In all (and other) of the

above circumstances analytical methods need to be validated. Reference guidance for validation of analytical methods is provided by ICH guidelines, which, however, are quite general and their application to the specific case of radiopharmaceuticals may require to be adapted, especially for those methods using "radio" detectors, such as gamma spectrometry, radio-HPLC or radio-TLC, and dose calibrators. Since validation may ultimately be considered as a useful way of increasing reliability and preventing out-of-specification cases in the day by day quality control of radiopharmaceuticals, the aim of this session is to strengthen the knowledge on validation of analytical methods, with special emphasis for those methods which are not adequately addressed by current applicable guidelines, such as radioanalytical methods. To overcome the above limitation, the EANM Radiopharmacy Committee and the European Pharmacopoeia's Expert Group for radiopharmaceutical preparations work jointly with the aim of defining and adapting the general principles set by the ICH guidelines to the specific cases of radiopharmaceuticals. The outcome of the joint work between the two Institutions will be presented during the session, together with an overview of radioanalytical techniques and principles of analytical method validation. Finally, with the aim of providing useful hints and tips to the audience, practical examples of typical situations that may require the validation of radioanalytical methods will also be presented.

Key Words
Analytical methods, Pharmacopoeia, ICH, Radiopharmaceuticals